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entitled (54) POLYPROPYLENE SUTURES.

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Related Art (56)

407,569(4403/66)	40.5; 87.4.
4402/66	40.5; 87.4; 09.4.
246,163(64,148/60)	47.7; 40.5.

The following statement is a full description of this invention, including the best method of performing it known to us :

X544-92-5D-27P.C.

This invention relates to a sterile ~~isotatic~~ isotactic polypropylene monofilament suture and to a method of making the same.

Sutures may be divided into two general classes: absorbable sutures which are absorbed in the human body and nonabsorbable sutures which remain in the body without change or are removed from the skin when the underlying tissues have healed. The polypropylene sutures of the present invention are of the second type; i.e., they are nonabsorbable in the human body.

The strongest polypropylene monofilaments can generally be made from resins of high molecular weight and high crystallinity. The processing conditions along with the resin physical properties determine the final filament properties, and it is known that to obtain the tenacity that is required of a surgical suture, the extruded polypropylene monofilament must be stretched to align the polymer molecules.

Some of the advantages of oriented ~~isotatic~~ isotactic polypropylene as a suture material are described in United States Patent No. 3,359,983. ~~Isotatic~~ Isotactic polypropylene monofilament is so highly inert that minimal tissue reaction occurs in the suture area.

It has long been recognized that the drawing or stretching of polypropylene monofilament that is required to impart the necessary tenacity for suture use reduces the flexibility of the resulting product and results in poor handling qualities. While the handling characteristics of the suture are difficult to define, a suture should not be wiry or stiff and should remain in the position in which it is placed until moved by the surgeon.

Generally speaking, a stiff suture that has poor handling characteristics is inelastic and will break upon stretching. The polypropylene sutures of the prior art were characterized by an ultimate elongation (the percent increase in the length of the monofilament when stretched at room temperature to the breaking point) of less than 25 percent. By contrast, the flexible polypropylene monofilaments of the present invention are characterized by an ultimate elongation of 35 to ~~about~~ 63 percent.

It is another disadvantage of the polypropylene monofilaments previously known that they exhibit memory and will tend to retain the shape of the package. Stated in another way, a monofilament that is packaged as a coil will to a large extent retain the coil form after removal from the package. This makes it difficult for the surgeon to handle and tie down the monofilament particularly in the large sizes, i.e., size 2/0 and above.

These problems have been resolved by the present invention which enables one to manufacture a polypropylene monofilament suture of satisfactory tenacity and knot strength while retaining the percent elongation and flexibility that is demanded by the surgeon.

~~Summary of the Invention:~~

It has now been discovered that the flexibility of an extruded, ~~isotatic~~ isotactic polypropylene suture can be greatly improved with little sacrifice in tensile strength by stretching under controlled conditions to about 6.6 times the original extruded length and then relaxing or shrinking the monofilament to between 91 percent and 76 percent of the stretched length.

The extruded polypropylene monofilament may be drawn at conventional temperatures, i.e., between ~~about~~ 260°F. and 325°F. At about 330°F., the monofilament is approaching the molten stage, and breakage can be a problem. The tenacity of the monofilament is somewhat higher if the drawing is effected at the low temperature (in the neighborhood of 260°F.). Thus a product, the tensile strength of which is suitable for suture use (tenacity 3.3 to ~~8.5~~ 7.9 grams per denier,) may be obtained with a draw ratio of about 6.6:1 at 260°F.-325°F. The preferred drawing temperature for practicing the present invention is 300°F.

The relaxing or shrinking of the monofilament is also carried out at an elevated temperature, which may be within the range of the drawing temperature, i.e., 260°F. to 325°F. Again, it is preferred to shrink the monofilament at a temperature of 300°F.

Monofilaments that have not contracted to 91 percent of the stretched length have an ultimate elongation of about 25%, a Young's Modulus greater than about 6 X 10^5 and are lacking in flexibility as determined on the Gurley tester. Filaments that have contracted more than 76 percent of the stretched length have an excellent hand but may be deficient in tensile strength. The preferred amount of shrinkage that results in a polypropylene suture of good hand and tensile strength is about 82-85 percent.

As indicated above, a stiff or wiry suture is difficult for the surgeon to handle and tie down. A flexible suture by contrast has a "dead" quality and may be characterized by the surgeon as "throwable." Fortunately, the hand of the monofilament suture can be related to certain physical characteristics that will enable one to predict its acceptability to the surgeon independent of such subjective parameters as throwability, deadness, flexibility, or hand. One instrument that has been specifically designed to measure the stiffness or flexibility of textile materials is the Gurley tester. The Gurley stiffness of a monofilament suture as measured by this instrument is a measure of the desirability of a suture from the standpoint of its handling characteristics.

Other physical characteristics of polypropylene monofilaments that may be directly related to the ease of handling by the surgeon are Young's Modulus, which is a measurement of flexibility, plastic flow, which is a measure of extendability, yield stress data and the percent elongation at the breaking point. These properties are an indication of the acceptability of a polypropylene mono-

filament to the surgeon. The method of determining these characteristics and their correlation with pliability are described below.

According to the invention therefore there is provided an isotactic polypropylene monofilament sterile suture, said isotactic polypropylene having the following characteristics:

Weight Average Molecular Weight	-294,000 to 316,000
Number Average Molecular Weight	-78,400 to 82,100
Tensile Strength	-3.9 to 8.9 grams/denier
Knot Strength	-3.3 to 7.9 grams/denier
Break Elongation	-36% to 62%
Young's Modulus	-3.13×10^5 p.s.i. to 5.23×10^5 p.s.i.

The diameter of the suture is preferably in the range of from 0.002 inches to 0.02 inches.

According to the invention there is also provided a needled surgical suture comprising an isotactic polypropylene suture attached to a surgical needle, said needle and said suture being sterile, said isotactic polypropylene having the following characteristics:

Weight Average Molecular Weight	- 294,000 to 316,000
Number Average Molecular Weight	- 78,400 to 82,100
Tensile Strength	- 3.9 to 8.9 grams/denier
Knot Strength	- 3.3 to 7.9 grams/denier
Break Elongation	- 36% to 62%
Young's Modulus	$- 3.13 \times 10^5$ p.s.i. to 5.23×10^5 p.s.i.

The diameter of the suture is preferably in the range of from 0.002 inches to 0.02 inches.

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According to the invention there is further provided a surgical suture package comprising a sterile enclosure and therein a sterile needled surgical suture comprising an isotactic polypropylene suture attached to the surgical needle, said isotactic polypropylene having the following characteristics:

Weight Average Molecular Weight	- 294,000 to 316,000
Number Average Molecular Weight	- 78,400 to 82,100
Tensile Strength	- 3.9 to 8.9 grams/denier
Knot Strength	- 3.3 to 7.9 grams/denier
Break Elongation	- 36% to 62%
Young's Modulus	- 3.13×10^5 p.s.i. to 5.23×10^5 p.s.i.

The diameter of the suture is preferably in the range of from 0.002 inches to 0.02 inches.

The invention finally includes a method of improving the flexibility and hand of an extruded isotactic polypropylene monofilament which comprises the steps of stretching said monofilament at a temperature in the range of 260°F. to 325°F. to 6.6 times its original length; and subsequently heating said monofilament at a temperature in the range of 285°-300°F. and permitting the stretched monofilament to contract to between 91% and 76% of its stretched length.

The invention will appear more clearly from the following detailed description when taken in connection with the following drawings which show by way of example a preferred embodiment of the inventive idea.

Figures 1a and 1b illustrate apparatus for extruding and drawing polypropylene monofilament in accordance with the invention.

Figure 2 is a perspective view of two godets that draw and orient the polypropylene monofilament.

Figure 3 is a perspective view of the godets shown in Figure 2 and illustrates the simultaneous drawing of four polypropylene monofilaments.

Figure 4 is a perspective view of a creel.

Figure 5 is an enlarged view partially in section of the lower left leg of the creel as viewed from the right in Figure 4, showing the creel in an extended position.

Figure 6 is a sectional view of the leg of the creel illustrated in Figure 5, showing the creel in a modified position.

Figure 7 is a sectional view of the leg of the creel illustrated in Figure 5, showing the creel in a retracted position.

Figure 8 is a sectional view of the leg of the creel on the line 8-8 of Figure 5.

Figure 9 is a perspective view of a Gurley stiffness tester.

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Figure 10 is a perspective view of a jig designed to be used with the Curley tester, and

Figure 11 is a sectional view on the Line 11-11 of Figure 10.

Figure 12 is a reproduction of a stress-strain curve, obtained by applying stress at a constant rate to a polypropylene strand that has been produced in accordance with the present invention.

~~Description of the Preferred Embodiment~~:

The preferred method for preparing the flexible polypropylene sutures of the present invention utilizes as the raw material pellets of isotactic ~~isotactic~~ polypropylene having a weight average molecular weight of from about 294,000 ~~299,000~~ to about 316,000 and a number average molecular weight of from about 78,400 to about 82,100. The computed ratio of MN_w/MW_n is 3.84. Polypropylene of this grade is available in both powder and pellet form. Pellets, the maximum diameter of which do not exceed one-quarter inch, may be used in the process to be described.

Referring now to the apparatus illustrated in Figures 1a and 1b and to the physical steps involved in extruding, orienting, and relaxing the polypropylene monofilament, the extruder 10 that is used to form the polypropylene monofilament has a cylindrical barrel 11 supported in a horizontal plane and terminating at one end at an adaptor section 12 which leads to an extrusion die 14. A longitudinal screw 16 is mounted for rotation within the barrel 11 and is driven by the sprocket gear 18 positioned at the end of the extruder that is remote from the die through the chain 19 and a variable speed motor not shown.

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Polypropylene pellets flow by gravity from the hopper 21 into the cylindrical barrel of the extruder and are moved by the screw 16 in the direction of the die. The temperature of the extruder is controlled by three electrical heating units 22, 23, and 24, which surround the barrel 11 and the die 14. A cooling jacket 25 surrounds that end of the extruder barrel that is most remote from the die and removes heat from that end of the screw 16 that lies beneath the hopper.

The die 14 is constructed with a long land length and may have one or more orifices. Preferably, the die orifice has an entrance angle of 20°. With this entrance angle, streamlined flow is obtained insuring uniform extrudate.

Polypropylene pellets, the maximum dimension of which is less than one-quarter inch, are placed in the hopper 21 and flow by gravity into the barrel 12 of the extruder which is at that point maintained at room temperature or below by water flowing through the cooling jacket 25. The screw 16 conveys the polypropylene pellets through the feeding zone 22 into the metering zone 23 of the extruder wherein the polypropylene pellets are compressed and metered. The melted polypropylene then passes through the die 14, the temperature of which is controlled by a heating jacket 24, and into a quenching bath 27, which may be a water bath. In normal operation, the feeding zone 22 is maintained at about 430°F., the metering zone 23 between 400°F. and 450°F., the die 14 between 400°F. and 450°F., and the quenching bath at ~~about~~ 75°F. to 85°F.

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The extruded monofilament 28 is solidified as it moves downwardly into the quench bath. The monofilament passes around the idler 30, over the roller 32, and is wrapped around the godets 33 and 34 to prevent the slipping that might otherwise occur as a result of stretching the monofilament to orient the same and increase its tensile strength.

The monofilament from the godet 33 is stretched and oriented by passing it through the heating chamber 36 and around the godets 38 and 39 which rotate at a higher peripheral velocity than the godets 33 and 34, thereby stretching the monofilament from 6 to 7 times its original length and orienting the monofilament. The manner of wrapping the polypropylene monofilament around the godets 38 and 39 is shown in Figures 2 and 3. Figure 3 illustrates the arrangement of four monofilaments extruded simultaneously through a die having four orifices. The temperature of the monofilament as it passes through the chamber 36 is maintained at about 260°F to 325°F.

The stretched and oriented monofilament from the godet 38 passes over the guides 40 and the reciprocating guide 41 and is collected on spool 42. The spools of polypropylene monofilament may be stored for further processing.

In the second stage processing of polypropylene, the monofilament is permitted to shrink. This step may be carried out by a discontinuous process whereby a fixed length of polypropylene monofilament is heated to about 285°F to 300°F. and permitted to shrink to between 91 ~~92~~ percent and 76 ~~75~~ percent of its original length.

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The discontinuous finishing process is illustrated in Figures 4 through 8. The polypropylene monofilament is transferred from spool 42 to a creel 43 by rotating the creel on its axel 44, power being supplied by the motor 46 through the pulleys 47 and 48 and the belt 49. The creel 43 may be conveniently constructed of channel iron with two-leg sections 50 and 52 that are welded at one end to a crossbar 53. The opposite ends of these leg sections slidably receive channel sections 54 and 55, which are welded to a crossbar 57. The position of the crossbar 57 is fixed with respect to the opposite crossbar 53 by the stay bolts 58 and 59 which pass through the channel section 54 and the leg section 50. Similar bolts 58' and 59' pass through the channel section 55 and the leg section 52. The long dimension of the creel measures 50-1/2 inches when extended as shown in Figure 4.

After a layer of polypropylene monofilament has been wound onto the creel 43, a retention strip 56 is fastened to the crossbar 53 of the creel by bolts 51, thereby compressing the polypropylene monofilaments between the retention strip and the end of the creel. A second retention strip 56' is bolted to the opposite crossbar 57 of the creel thereby preventing the polypropylene from shifting during the heat-shrinking step. When the retention strips are in position, the creel is supported on its axel 44 with the movable crossbar 57 of the creel in its lower-most position, and the stay bolts 58, 59, 58' and 59' are removed from each leg of the creel. The channel sections 54 and 55 are then telescoped into the legs 50 and 52 a distance corresponding to the desired amount of shrinkage and the stay bolts replaced. The creel is then placed in an oven main-

tained at 300°F. and rotated at 5-20 r.p.m. to insure uniform heating. At this temperature, the polypropylene that is wrapped on the creel shrinks causing the channel sections 54 and 55 of the creel to telescope into the leg sections 50 and 52 as indicated by Figure 6. The creel is removed from the oven after 10 minutes and is permitted to cool to room temperature. The position of the end 57 of the creel after the heat-shrinking step is shown in Figure 7. As indicated above, the creel in its extended position (Figure 5) has a length of 50-1/2 inches, which may be reduced to 42 inches (Figure 7) after shrinkage of each 50-1/2 inch length of polypropylene amounts to 8-1/2 inches (from 50-1/2 inches to 42 inches in increments that permit shrinking of the monofilament from 91 percent to 75.6 percent.

Straight polypropylene monofilaments 42 inches in length are removed from the creel by cutting the filaments at the opposite ends 53 and 57 of the creel. Needles may be swaged to one end of the monofilaments so obtained. The heat-relaxed monofilaments with or without needles attached thereto are cooled, packaged, and sterilized for use as surgical sutures.

The present invention will be further illustrated by the following examples which describe the manufacture of polypropylene sutures (size 2 through 7/0) and the physical properties thereof. In all of the following examples ~~isotatic~~ isotactic polypropylene is used having a weight average molecular weight of between ~~about~~ 294,000 and ~~about~~ 316,000 and a number average molecular weight of between ~~about~~ 78,400 and

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~~bout~~ 82,100. To this resin is added 0.5 percent by weight of copper phthalocyanine dye, which imparts a dark blue color to the resin and the monofilaments extruded therefrom.

Heat stabilizers and other processing compounds known in the art may be added to improve the resistance to oxidation during the extrusion and processing steps. Compounds commonly used for this purpose are tertiary butyl-o-cresol ~~(IONOL)~~ together with dilauryl thio-propionate in amounts of about 0.25% each.

The tensile strength and percent elongation at break reported in Examples I through XIII are determined by A.S.T.M. method D-2256-66T using a constant rate of extension tester, namely a table model INSTRON universal testing instrument manufactured by the Instron Corporation of Canton, Massachusetts. This test method is described in the 1966 Book of A.S.T.M. Standards, part 24 (published in August of 1966 by the American Society for Testing Material, 1916 Race Street, Philadelphia, Pennsylvania). The 20 seconds to break is approximated by using a one-inch sample (or gauge length) with the INSTRON Tester cross-head speed set at one inch per minute. ("INSTRON" is a Registered Trade Mark).

The knot strength is determined by the test method described in the U.S. Pharmacopeia, Vol. XVII, page 921.

Young's Modulus is determined on a Table Model INSTRON instrument using line contact jaw faces to minimize slippage. A 10.0 inch sample is elongated at the rate of 5.0 inches per minute (cross-head speed), the chart speed is 20.0 inches per minute. It has been noted that the pliability of a polypropylene suture may be correlated with its behavior under stress. Physical tests that may be used to reliably evaluate the subjective characteristics of "hand," flexibility, and extensibility are described in Example I.

The Gurley stiffness is measured with a motor-operated Gurley Stiffness Tester (Model 4171) manufactured

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by W. and L.E. Gurley of Troy, New York. This instrument, illustrated in Figure 9, consists of a balanced pendulum or pointer 60, which is center pivoted and which can be variously weighted below its center with a removable weight 61. The pointer moves parallel to a "sine" scale 62 graduated in both directions. In the test, ten, 2-inch polypropylene monofilament strands, a total of at least 20 inches, are required per sample. The strands used should be relatively straight.

The ten, 2-inch strands 63 are inserted in the jig illustrated in Figures 10 and 11. The jig is constructed with 10 parallel holes drilled on 1/8-inch centers. The polypropylene strands are inserted so that at least 1 inch of each strand protrudes beyond the bending bar 64, and a locking pin 65 is inserted to clamp the monofilaments in the jig.

A razor blade is used to shave closely the strand tips which extend from the back of the jig, and all ten strands are cut 1 inch from the edge of the bending bar 64 on the opposite side of the clamp.

The jig is placed on the motor-driven arm 68 of the Gurley instrument so that the clamp-bending bar lies 1/2 inch above the edge 70 of the swinging pendulum. When the motor-driven arm 68 presses the monofilaments 63 against the edge 70 of the pendulum, the pointer is deflected until the sample scrapes past the pendulum and may be read on the scale 62. The resistance of the pendulum and thus the sensitivity of the machine to materials of different stiffness can be adjusted in two ways: by changing the distance

from the fulcrum 67 of the weight 61 and by changing the weight itself.

The machine is operated for one or two cycles to adjust the weight-distance combination if necessary. This adjustment should be made so that the average reading will fall between 2.0 and 7.0 Gurley units. (A cycle is defined as a left plus a right swing of the pointer 60. A Gurley unit is the unit reading marked on the sine scale.) After the necessary adjustments are made, the machine is operated for ten cycles without recording the results. After each half cycle, the oscillation of the pendulum is stopped before continuing. The readings of cycles 11 through 15 are recorded and averaged. The stiffness of the polypropylene monofilament sample may then be calculated by use of the following formula:

Gurley stiffness (mg.) - 0.0002 RWD, where

R - test reading in Gurley units

W - counterweight (gm.)

D - distance of counterweight from fulcrum (inches)

The present invention will be further illustrated by the following examples which describe the manufacture of polypropylene sutures of different sizes, all of which have a Young's Modulus below 6×10^5 p.s.i. and an elongation at break of at least 35%.

EXAMPLE I

All Viscoelastic measurements reported in the tables are made on a Table Model INSTRON Tensile Tester using a Type C Tension Cell; full-scale range 1 to 50 pounds. The measurements are made in an air-conditioned

laboratory at 72°F. and 50% relative humidity. To hold the specimen suture strand, two line contact jaws are used. The diameter of the strand is measured to 0.0001 inches and the area of the strand is calculated. A 10 inch sample is placed between the jaws and both jaws closed, under 20 p.s.i. air pressure. The area compensator on the INSTRON Tester is set for the correct diameter of the suture (to give a read-out in p.s.i.) and the strand is elongated at a constant rate to 112.5% of the original length (pre-set on the INSTRON). The INSTRON machine is operated at a cross-head speed of 5 inches per minute and a chart speed of 20 inches per minute.

Stress-strain curves produced under these conditions have the general shape illustrated in Figure 12. Young's Modulus (p.s.i. X 10^5) is the initial modulus as determined from the slope of the curve A of Figure 12. Young's Modulus is the ratio of applied stress to strain in the elastic region and measures the elastic component of a suture's resistance to stress. This value is related to the flexibility of a suture.

Plastic flow (p.s.i. X 10^5) is the viscoelastic modulus as determined from the slope of the curve B of Figure 12. It measures the plastic component of a suture's resistance to stress and is related to the "give" a suture exhibits under a force in excess of the yield stress.

The yield stress (p.s.i. X 10^4) is the first point of inflection in the stress-strain curve or the point of intersection C of the slopes A and B of Figure 12. Yield Stress measures the force required to initiate viscoelastic flow and is related to the straightenability of a suture.

Typical pliability data as determined from the stress-strain curves of the polypropylene sutures of the present invention is summarized in Table I. The date is obtained after aging the sample for one month.

TABLE I

Pliability Values

Size	Young's Modulus
2	3.23×10^5
1	3.13×10^5
0	3.54×10^5
2/0	4.05×10^5
3/0	4.47×10^5
4/0	4.13×10^5
5/0	3.42×10^5
7/0	4.49×10^5

EXAMPLE II

A size 7/0 polypropylene suture, diameter 2.6 mils., is prepared by the general procedure described above. The die orifice measures 20 mils. in diameter, and the flow rate of the polypropylene through the die orifice is 0.06 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 450°F. The ratio of the rate of takeup of the godet 33 to the linear rate of extrusion (draw ratio) is 5.9. The water bath is maintained at 75-84°F.

The heating chamber is seven feet in length and is maintained at 285°F., as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 50 feet per minute and is taken up on the godet 38

at the linear rate of 330 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 285°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (from 50-1/2 to 42 inches or 83.5%).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. for 10 minutes with no relaxation. Thelength of the monofilament is 52-1/2 inches prior to and after the ten minute heat treatment at 300°F. The following table shows the differences in the physical properties of polypropylene monofilament that has been (1) hot stretched 6.6 X while maintaining the temperature at 285°F.; (2) hot stretched 6.6 X its original length while maintaining the temperature at 285°F. and then annealing for ten minutes at 300°F. without relaxation; and (3) hot stretched 6.6 X its original length while maintaining the temperature at 285°F. and then annealing for ten minutes at 300°F. while relaxing to 5.5 X its original length (83.5% of its hot stretched length). The data is obtained after aging the samples for one month.

TABLE II

	(1) Polypropylene Stretched 6.6:1	(2) Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 minutes	(3) Polypropylene Stretched 6.6:1 and Relaxed to 83.5% of Stretched Length
Lot Number	115325	115325	115325
Diameter, mils	2.4	2.3	2.6
Denier	24	22	28
Tensile Strength			
Grams/Denier	9.8	8.5	8.9
P.S.I. X 10^{-3}	11.26	12.15	10.16
Knot Strength			
Grams/Denier	7.7	8.8	7.9
P.S.I. X 10^{-3}	8.83	9.28	9.03
Break Elongation	27%	37%	41%
Gurley Stiffness	1 mg.	1 mg.	1 mg.
Young's Modulus psi	9.50 X 10^5	8.03 X 10^5	4.49 X 10^5

EXAMPLE III

A size 5/0 polypropylene suture, diameter 4.9 mils, is prepared by the general procedure described above. The die orifice measures 20 mils in diameter, and the flow rate of the polypropylene through the die orifice is 0.09 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 450°F. The ratio of the rate of takeup of the godet 33 to the linear rate of extrusion (draw ratio) is 2.32. The water bath is maintained at 75-84°F.

The heating chamber is seven feet in length and is maintained at 285°F. as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 30 feet per minute and is taken up on the godet 38 at the linear rate of 198 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 285°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (from 50-1/2 to 42 inches or 83.5 percent).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F. The physical properties of the product so obtained are summarized in the following table. The data is obtained after aging the samples for one month.

TABLE III

	(1) Polypropylene Stretched 6.6:1	(2) Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 minutes	(3) Polypropylene Stretched 6.6:1 and Relaxed to 83.[illegible]% of Stretched Length
Lot Number	107925	107925	107925
Diameter, mils	4.9	5.0	5.2
Denier	98	102	110
Tensile Strength			
Grams/Denier	6.5	6.7	5.7
P.S.I. X 10^{-3}	7.42	7.63	6.59
Knot Strength			
Grams/Denier	5.8	5.4	5.4
P.S.I. X 10^{-3}	6.62	6.21	6.21
Break Elongation	27%	30%	38%
Gurley Stiffness	4.1 mg.	3.4 mg.	3.4 mg.
Young's Modulus psi	7.15 X 10^5	6.49 X 10^5	3.42 X 10^5

EXAMPLE IV

A size 4/0 polypropylene suture, diameter 6.9 mils, is prepared by the general procedure described above. The die orifice measures 34 mils in diameter, and the flow rate of the polypropylene through the die orifice is 0.24 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 430°F. The ratio of the rate of takeup of the godet 33 to the linear rate of extrusion (draw ratio) is 3.62. The water bath is maintained at 75-84°F. The data is obtained after aging the samples for one month.

The heating chamber is seven feet in length and is maintained at 295°F. as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 40 feet per minute and is taken up on the godet 38 at the linear rate of 264 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (from 50-1/2 to 42 inches or 83.5%).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F. The difference in the physical properties of polypropylene monofilament that has been drawn, annealed without relaxation and heat relaxed to 83.5 percent of its original length is summarized in the following table. The data is obtained after aging the sample for one month.

TABLE IV

	(1) Polypropylene Stretched 6.6:1	(2) Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 Minutes	(3) Polypropylene Stretched 6.6:1 and Relaxed to 83.5% of Stretched Length
Lot Number	107930	107930	107930
Diameter, mils	6.9	6.8	7.4
Denier	194	189	223
Tensile Strength			
Grams/Denier	5.7	6.7	5.9
P.S.I. X 10^{-3}	7.75	7.70	6.74
Knot Strength			
Grams/Denier	4.4	4.7	4.5
P.S.I. X 10^{-3}	5.08	5.37	5.10
Break Elongation	21%	28%	36%
Gurley Stiffness	15.5 mg.	11.4 mg.	12.4 mg.
Young's Modulus psi	8.90 X 10^5	7.26 X 10^5	4.13 X 10^5

EXAMPLE V

A size 3/0 polypropylene suture, diameter 8.6 mils, is prepared by the general procedure described above. The die orifice measures 34 mils in diameter, and the flow rate of the polypropylene through the die orifice is 0.24 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 430°F. The ratio of the rate of takeup of the godet 33 to the linear rate of extrusion (draw ratio) is 2.26. The water bath is maintained at 75-84°F.

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The heating chamber is seven foot in length and is maintained at 260°F. as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 25 feet per minute and is taken up on the godet 38 at the linear rate of 165 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (from 50-1/2 to 42 inches or 83.5 percent).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F. The difference in the physical properties of polypropylene monofilament that has been drawn, annealed without relaxation and heat relaxed to 83.5 percent of its original length is summarized in the following table. The data is obtained after aging the samples for one month.

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	(1) Polypropylene Stretched 6.6:1	(2) Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 Minutes	(3) Polypropylene Stretched 6.6:1 and Relaxed to 83.5% of Stretched Length
Lot Number	107946	107946	107946
Diameter, mils	8.6	8.4	9.1
Denier	302	288	338
Tensile Strength			
Grams/Denier	5.9	6.3	5.4
P.S.I. X 10^{-3}	6.71	7.21	6.14
Knot Strength			
Grams/Denier	4.1	4.4	4.3
P.S.I. X 10^{-3}	4.64	5.08	4.98
Break Elongation	25%	34%	41%
Gurley Stiffness	29.0 mg.	25.0 mg.	22.0 mg.
Young's Modulus psi	8.21 X 10^5	6.84 X 10^5	4.47 X 10^5

EXAMPLE VI

A size 2/0 polypropylene suture, diameter 11.1 mils., is prepared by the general procedure described above. The die orifice measures 54 mils in diameter, and the flow rate of the polypropylene through the die orifice is 0.60 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 430°F. The ratio of the rate of takeup of the godet 33 to the linear rate of extrusion (draw ratio) is 3.33. The water bath is maintained at 75-84°F.

The heating chamber is seven feet in length and is maintained at 230°F. as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 38 feet per minute and is taken up on the godet 38 at the linear rate of 250 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (from 50-1/2 to 42 inches or 83.5 percent).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F. The difference in the physical properties of polypropylene monofilament that has been drawn annealed without relaxation and heat relaxed to 83.5 percent of its original length is summarized in the following table. The data is obtained after aging the samples for one month.

TABLE VI

	(1) Polypropylene Stretched 6.6:1	(2) Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 Minutes	(3) Polypropylene Stretched 6.6:1 and Relaxed to 83.5% of Stretched Length
Lot Number	115358	115358	115358
Diameter, mils	11.1	11.3	12.4
Denier	503	521	627
Tensile Strength			
Grams/Denier	5.4	5.7	4.8
P.S.I. X 10^{-3}	6.19	6.48	5.46
Knot Strength			
Grams/Denier	3.9	3.9	3.5
P.S.I. X 10^{-3}	4.44	4.48	4.05
Break Elongation	25 %	34 %	38 %
Curley Stiffness	68.0 mg.	55.0 mg.	61.0 mg.
Young's Modulus psi	6.48 X 10^5	6.95 X 10^5	4.05 X 10^5

EXAMPLE VII

A size 0 polypropylene suture, diameter 13.8 mils., is prepared by the general procedure described above. The die orifice measures 54 mils in diameter, and the flow rate of the polypropylene through the die orifice is 0.59 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 430°F. The ratio of the rate of takeup of the godet 33 to the linear rate of extrusion (draw ratio) is 2.22. The water bath is maintained at 75-84°F.

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The heating chamber is seven feet in length and is maintained at 240°F. as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 25 feet per minute and is taken up on the godet 38 at the linear rate of 165 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (from 50-1/2 to 42 inches or 83.5%).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F. The difference in the physical properties of polypropylene monofilament that has been drawn annealed without relaxation and heat relaxed to 83.5 percent of its original length is summarized in the following table. The data is obtained after aging the samples for one month.

TABLE VII

	(1) Polypropylene Stretched 6.6:1	(2) Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 Minutes	(3) Polypropylene Stretched 6.6:1 and Relaxed to 83.5% of Stretched Length
Lot Number	107947	107947	107947
Diameter, mils	13.8	14.0	14.8
Denier	773	798	894
Tensile Strength			
Grams/Denier	5.1	5.3	4.7
P.S.I. X 10^{-3}	5.88	6.04	5.40
Knot Strength			
Grams/Denier	3.8	3.9	3.4
P.S.I. X 10^{-3}	4.41	4.41	3.95
Break Elongation	27%	36%	53 %
Gurley Stiffness	159.0 mg.	134.0 mg.	124.0 mg.
Young's Modulus psi	6.33 X 10^5	5.73 X 10^5	3.54 X 10^5

EXAMPLE VIII

A size 1 polypropylene suture, diameter 16.1 mils., is prepared by the general procedure described above. The die orifice measures 54 mils in diameter, and the flow rate of the polypropylene through the die orifice is 0.80 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 430°F. The ratio of the rate of takeup of the godet 33 to the linear rate of extrusion (draw ratio) is 1.61. The water bath is maintained at 75-84°F.

The heating chamber is seven feet in length and is maintained at 255°F. as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 23 feet per minute and is taken up on the godet 38 at the linear rate of 152 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (from 50-1/2 to 42 inches or 83.5 percent).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F. The difference in the physical properties of polypropylene monofilament that has been drawn annealed without relaxation and heat relaxed to 83.5 percent of its original length is summarized in the following table. The data is obtained after aging the samples for one month.

TABLE VIII 16,926/70

	(1) Polypropylene Stretched 6.6:1	(2) Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 Minutes	(3) Polypropylene Stretched 6.6:1 and Relaxed to 83.5% of Stretched Length
Lot Number	107942	107942	107942
Diameter, mils	16.1	16.4	18.1
Denier	1,058	1,097	1,339
Tensile Strength			
Grams/Denier	5.2	5.2	4.4
P.S.I. X 10^{-3}	5.99	5.86	5.01
Knot Strength			
Grams/Denier	3.8	3.7	3.4
P.S.I. X 10^{-3}	4.37	4.21	3.88
Break Elongation	31%	40%	51%
Gurley Stiffness	262.0 mg.	240.0 mg.	232.0 mg.
Young's Modulus psi	6.25×10^5	5.72×10^5	3.13×10^5

EXAMPLE IX

A size 2 polypropylene suture, diameter 19.4 mil is prepared by the general procedure described above. The die orifice measures 64 mils in diameter, and the flow rate of the polypropylene through the die orifice is 1.1 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 430°F. The ratio of the rate of takeup of the godet 33 to the linear rate of extrusion (draw ratio) is 1.70. The water bath is maintained at 75-84°F.

The heating chamber is seven feet in length and is maintained at 230°F. as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 26 feet per minute and is taken up on the godet 38 at the linear rate of 168 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (from 50-1/2 to 42 inches or 83.5 percent).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F. The difference in the physical properties of polypropylene monofilament that has been drawn, annealed without relaxation and heat relaxed to 83.5 percent of its original length is summarized in the following table. The data is obtained after aging the samples for one month.

TABLE IX

	(1) Polypropylene Stretched 6.6:1	(2) Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 Minutes	(3) Polypropylene Stretched 6.6:1 and Relaxed to 83.5% of Stretched Length
Lot Number	115351	115351	115351
Diameter, mils	19.4	19.4	20.5
Denier	1,536	1,536	1,714
Tensile Strength			
Grams/Denier	4.2	4.6	3.9
P.S.I. X 10^{-3}	4.80	5.24	4.44
Knot Strength			
Grams/Denier	3.0	3.3	3.3
P.S.I. X 10^{-3}	3.45	3.79	3.81
Break Elongation	34%	37%	62%
Gurley Stiffness	370.7 mg.	392.0 mg.	328.0 mg.
Young's Modulus psi	5.47×10^5	4.97×10^5	3.22×10^5

EXAMPLE X16.926/70

A size 3/0 polypropylene suture, diameter 9.14 mils., is prepared by the general procedure described in Example V. Instead of stretching the polypropylene monofilament 6.6 times, however, it is stretched 6.0 times its original length in a heating chamber maintained at 260°F.

The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 5-1/2 times its original length (91.6%).

In a control experiment, polypropylene from the same extrusion batch (stretched 6.0 times its original length) is removed from the take-up spool 42, placed on the creel and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F.

The difference in the physical properties of polypropylene monofilament that has been drawn, annealed without relaxation and heat relaxed to 91.6 percent of its stretched length is summarized in the following table. The data is obtained after aging the samples for one month.

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TABLE X 16.926/70

	Polypropylene Stretched 6.0:1	Polypropylene Stretched 6.0:1 and Annealed at 300°F. for 10 minutes	Polypropylene Stretched 6.0:1 and Relaxed to 91.6% of Stretched Length
Lot Number	127642-A1	127642-A2	127642-A3
Diameter, mils.	9.14	9.15	9.61
Denier	341	342	376
Tensile Strength			
Grams/Denier	4.7	5.3	4.8
P.S.I. X 10^{-3}	5.44	6.06	5.47
Knot Strength			
Grams/Denier	3.5	4.1	4.0
P.S.I. X 10^{-3}	4.04	4.66	4.53
Break Elongation	26%	36%	37%
Gurley Stiffness	31.3 mg.	26.5 mg.	28.0 mg.
Young's Modulus psi	8.95 X 10^5	7.76 X 10^5	6.27 X 10^5

EXAMPLE XI

A size 3/0 polypropylene suture, diameter 8.84 mils., is prepared by the general procedure described above in Example V. Instead of stretching the polypropylene monofilament 6.6:1, however, it is stretched seven times its original length in a heating chamber maintained at 260°F. The polypropylene monofilament after hot stretching is transferred to the creel 43 illustrated in Figs. 4-8 and permitted to shrink to 5.5 times its stretched length by heating for 10 minutes at 300°F.

In a control experiment, polypropylene from the same extrusion batch (stretched 7.0 times its original length) is removed from the take-up spool 42, placed on the

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creel and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F.

The difference in the physical properties of polypropylene monofilament that has been drawn, annealed without relaxation, and heat relaxed to 78.5% of its stretched length is summarized in the following table. The data is obtained after aging the samples for one month.

TABLE XI

	Polypropylene Stretched 7.0:1	Polypropylene Stretched 7.0:1 and Annealed at 300°F. for 10 min.	Polypropylene Stretched 7.0:1 and Relaxed to 78.6% of Stretched Length
Lot Number	127642-C1	127642-C2	127642-C3
Diameter, mils.	8.54	8.45	9.60
Denier	298	291	376
Tensile Strength			
Grams/Denier	6.0	5.3	4.7
P.S.I. X 10^{-3}	6.82	6.08	5.41
Knot Strength			
Grams/Denier	3.9	4.1	3.8
P.S.I. X 10^{-3}	4.41	4.70	4.33
Break Elongation	25%	23%	41%
Curley Stiffness	22.7 mg.	22.5 mg.	21.2 mg.
Young's Modulus psi	11.23×10^5	9.35×10^5	6.16×10^5

EXAMPLE XII

A size 0 polypropylene suture, diameter 13.9 mils., is prepared by the general procedure described above in Example VII. The die orifice measures 54 mils. in diameter, and the flow rate of the polypropylene through the die orifice

is 0.59 pounds per hour. The temperature of the feed zone is maintained at 430°F., and the temperature of the die and extruder barrel is maintained at 430°F. The ratio of the rate of take-up of the godet 33 to the linear rate of extrusion (draw ratio) is 2.22. The water bath is maintained at 75°-84°F.

The heating chamber is seven feet in length and is maintained at 240°F. as measured with a pyrometer. The polypropylene monofilament enters the chamber at the linear rate of 25 feet per minute and is taken up on the godet 38 at the linear rate of 165 feet per minute (stretched 6.6 times its original length). The polypropylene monofilament after hot stretching is collected on the take-up spool 42 and transferred to the creel 43 illustrated in Figures 4-8. The tension strips are applied to either end of the creel and the distance between the crossbars 53 and 57 is adjusted by the stay bolts 58, 59, 58' and 59' to permit the desired amount of shrinkage. The creel is then heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes; during which time the monofilament shrinks to 6.0 times its stretched length.

In a control experiment, polypropylene from the same extrusion batch (stretched 6.6 times its original length) is removed from the take-up spool 42, placed on the creel, and heated in an oven at 300°F. and rotated at 10 r.p.m. for 10 minutes with no relaxation. The length of the monofilament is 52-1/2 inches prior to and after the 10-minute heat treatment at 300°F. The difference in the physical properties of polypropylene monofilament that has been drawn, annealed without relaxation and heat relaxed to 91 percent of its stretched length is summarized in the following table. The data obtained after aging the sample for one week is as follows.

TABLE XII

	Polypropylene Stretched 6.6:1	Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 min.	Polypropylene Stretched 6.6:1 and Relaxed to 91% of Stretched Length
Lot Number	110805D	127642-C2	110842B
Diameter, mils.	13.9	8.45	14.4
Denier	788	291	822
Tensile Strength			
Grams/Denier	5.1	5.3	5.1
P.S.I. X 10^{-3}	5.86	6.08	5.83
Knot Strength			
Grams/Denier	3.8	4.1	3.8
P.S.I. X 10^{-3}	4.35	4.70	4.36
Break Elongation	27%	23%	42%
Gurley Stiffness	148.0 mg.	25.0 mg.	128.0 mg.
Young's Modulus psi	6.72 X 10^5	9.78 X 10^5	5.23 X 10^5

EXAMPLE XIII

A size 0 polypropylene suture, diameter 13.9 mils., is prepared by the general procedure described in Example XII, except that after the polypropylene monofilament is hot stretched to 6.6 times its original length, it is relaxed to 5.0 times its original length. The difference in the physical properties of polypropylene monofilament that has been drawn, annealed without relaxation and heat relaxed to 76 percent of the stretched length is summarized in the following table. The data is obtained after aging the sample for one week.

TABLE XIII

	Polypropylene Stretched 6.6:1	Polypropylene Stretched 6.6:1 and Annealed at 300°F. for 10 min.	Polypropylene Stretched 6.6:1 and Relaxed to 91% of Stretched Length
Lot Number	1108050	127642-C2	110842D
Diameter, mils.	13.9	8.45	15.6
Denier	788	291	992
Tensile Strength			
Grams/Denier	5.1	5.3	4.2
P.S.I. X 10^{-3}	5.86	6.08	4.81
Knot Strength			
Grams/Denier	3.8	4.1	3.3
P.S.I. X 10^{-3}	4.35	4.70	3.76
Break Elongation	27 %	23%	59%
Gurley Stiffness	148.0 mg.	25.0 mg.	132.0 mg.
Young's Modulus psi	6.72 X 10^5	9.78 X 10^5	3.31 X 10^5

While both monofilament and braided multifilament sutures are commonly used in the operating room, the monofilament structure is preferred by many surgeons. Polypropylene monofilament sutures prepared as described above are easy to use and tie because of their flexibility. The polypropylene sutures may be attached to surgical needles, sterilized with ethylene oxide and packaged in sterile containers for use in the operating room.

THE CLAIMS DEFINING THE INVENTIONS ARE AS FOLLOWS:-

1. An isotactic polypropylene monofilament sterile suture, said isotactic polypropylene having the following characteristics:

Weight Average Molecular Weight	- 294,000 to 316,000
Number Average Molecular Weight	- 78,400 to 82,100
Tensile Strength	- 3.9 to 8.9 grams/denier
Knot Strength	- 3.3 to 7.9 grams/denier
Break Elongation	- 36% to 62%
Young's Modulus	- 3.13×10^5 p.s.i. to 5.23×10^5 p.s.i.

2. An isotactic polypropylene monofilament sterile suture as claimed in claim 1, the suture having a diameter in the range of from 0.002 inches to 0.020 inches.

3. A needled surgical suture comprising an isotactic polypropylene suture attached to a surgical needle, said needle and said suture being sterile, said isotactic polypropylene having the following characteristics:

Weight Average Molecular Weight	- 294,000 to 316,000
Number Average Molecular weight	- 78,400 to 82,100
Tensile Strength	- 3.9 to 8.9 grams/denier
Knot Strength	- 3.3 to 7.9 grams/denier
Break Elongation	- 36% to 62%
Young's Modulus	- 3.13×10^5 p.s.i. to 5.23×10^5 p.s.i.

4. A needled surgical suture as claimed in claim 3, the suture having a diameter in the range of from 0.002 inches to 0.020 inches.

5. A surgical suture package comprising a sterile enclosure and therein a sterile needled surgical suture comprising an isotactic polypropylene suture attached to the surgical needle, said isotactic polypropylene having the following characteristics:

Weight Average Molecular Weight	- 294,000 to 316,000
Number Average Molecular Weight	- 78,400 to 82,100
Tensile Strength	- 3.9 to 8.9 grams/denier
Knot Strength	- 3.3 to 7.9 grams/denier
Break Elongation	-36% to 62%
Young's Modulus	- 3.13×10^5 p.s.i. to 5.23×10^5 p.s.i.

6. A surgical suture package as claimed in claim 5, the suture having a diameter in the range of from 0.002 inches to 0.02 inches.

7. A method of improving the flexibility and hand of an extruded isotactic polypropylene monofilament which comprises the steps of stretching said monofilament at a temperature in the range of 260°F. to 325°F. to 6.6 times its original length; and subsequently heating said monofilament at a temperature in the range of 285°-300°F. and permitting the stretched monofilament to contract to between 91% and 76% of its stretched length.

Dated this 4th day of October, 1973.

ETHICON, INC.
By their Patent Attorney:

of ~~GRIFFITH, HASSEL & FRAZER.~~

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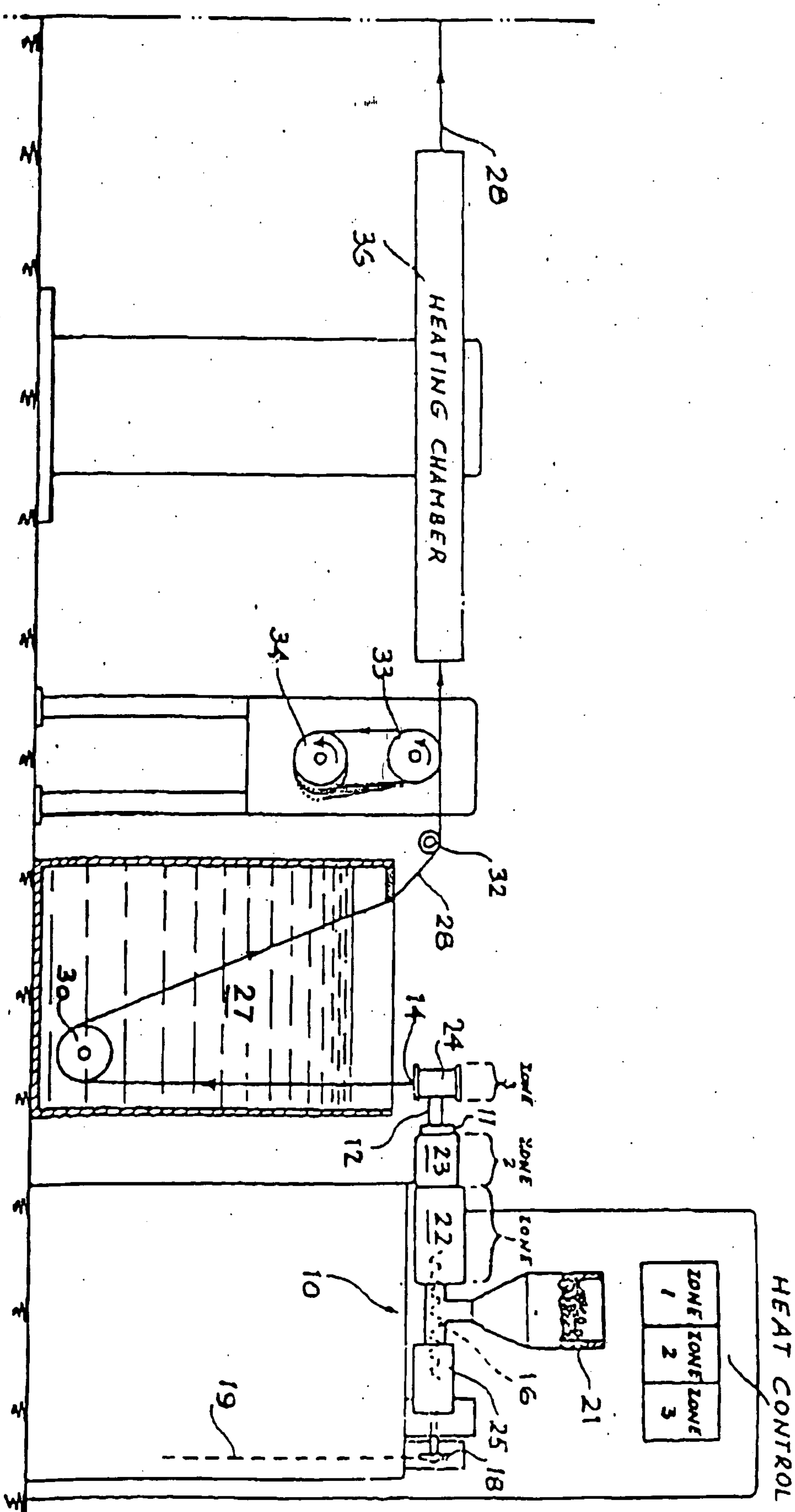

FIG. 1a

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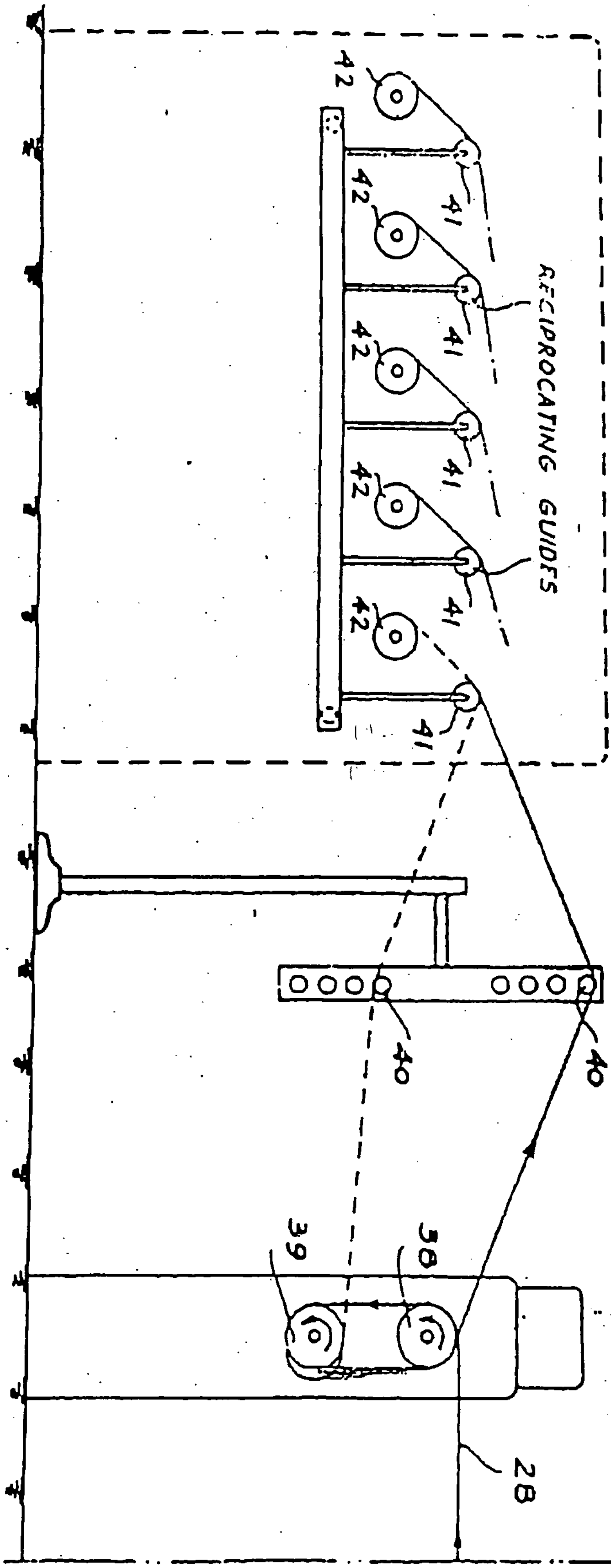

FIG. 1b

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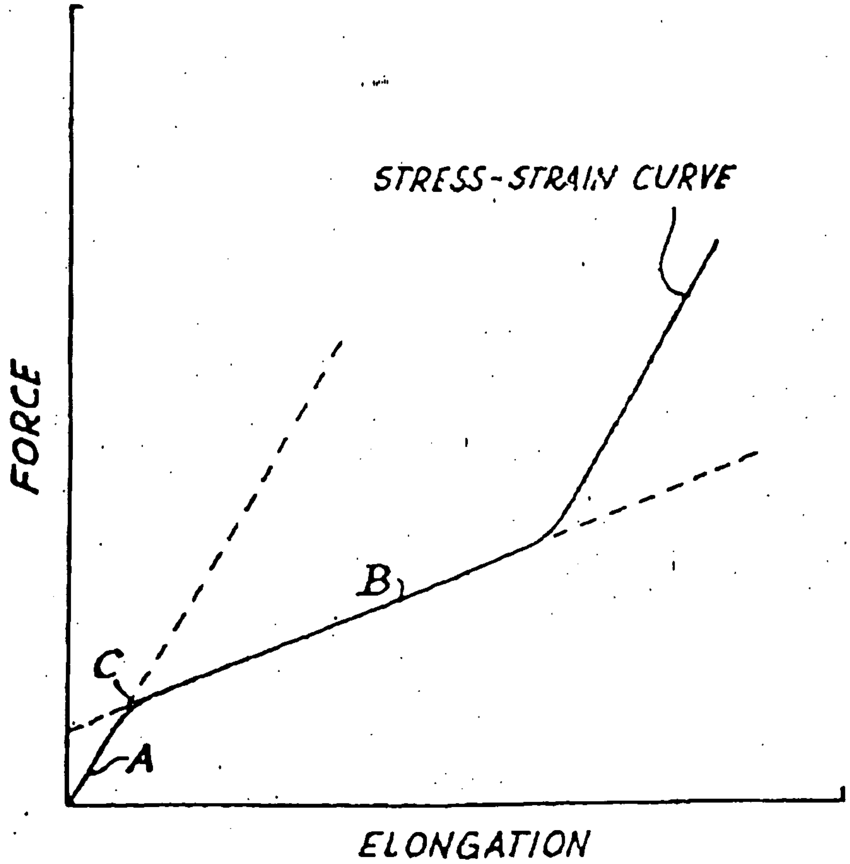
FIG. 12



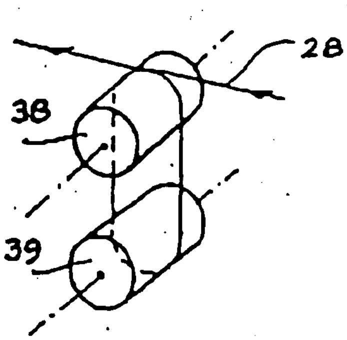


FIG. 2

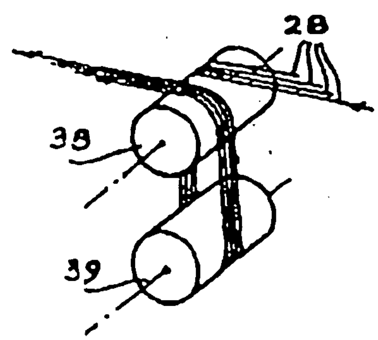


FIG. 3

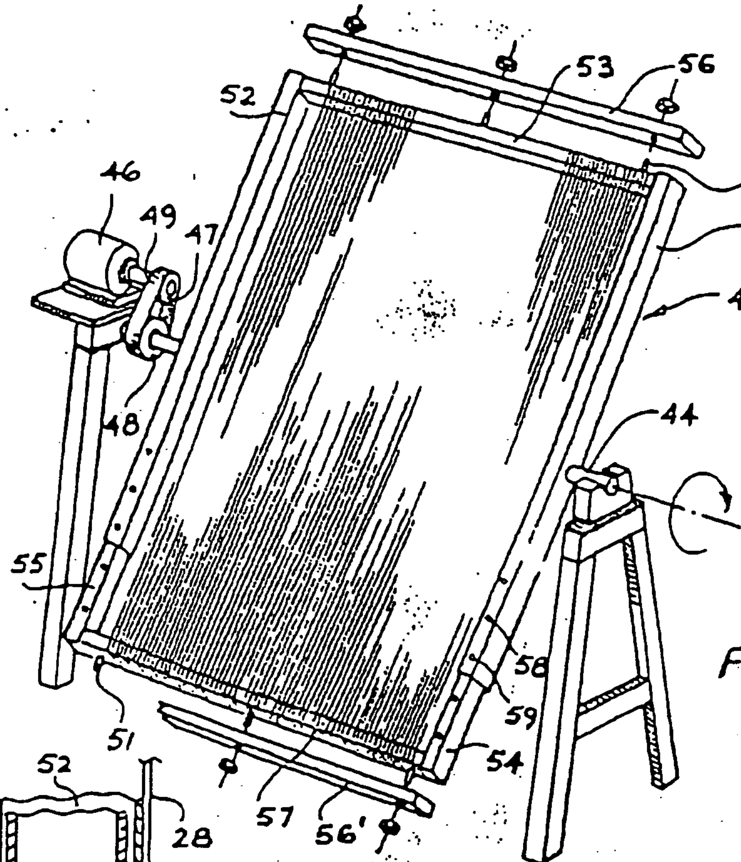


FIG. 4

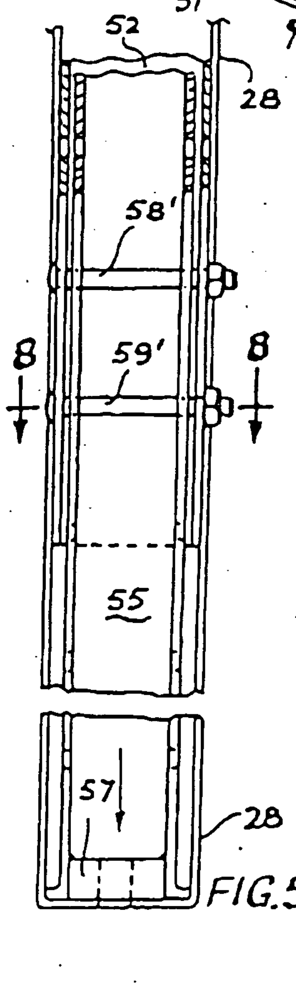


FIG. 5

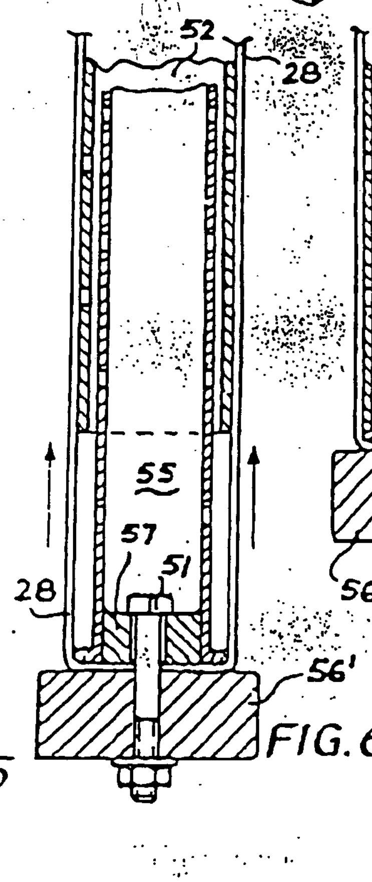


FIG. 6

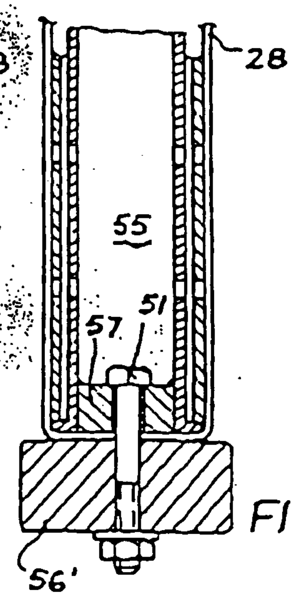


FIG. 7

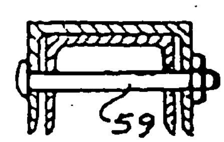


FIG. 8

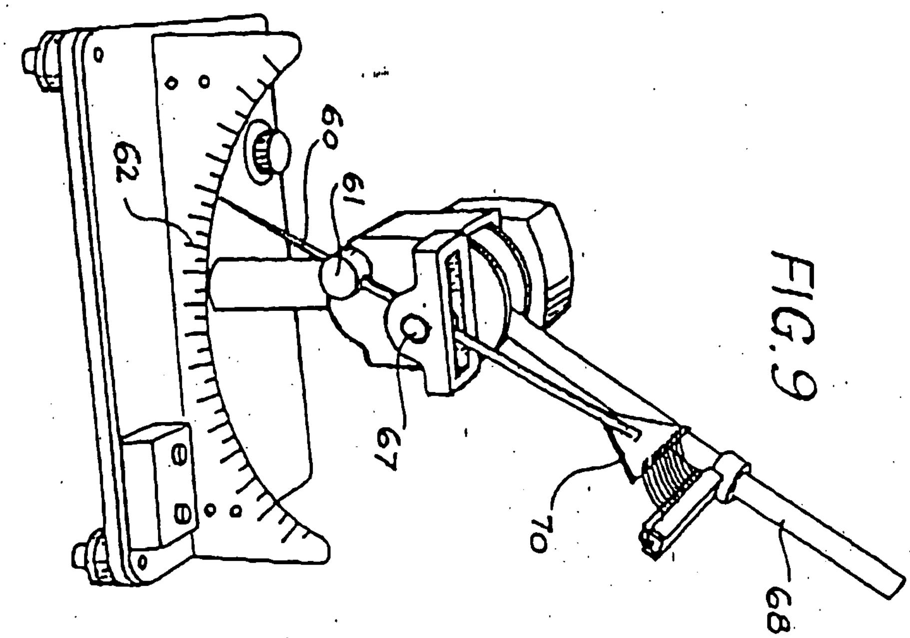


FIG. 9

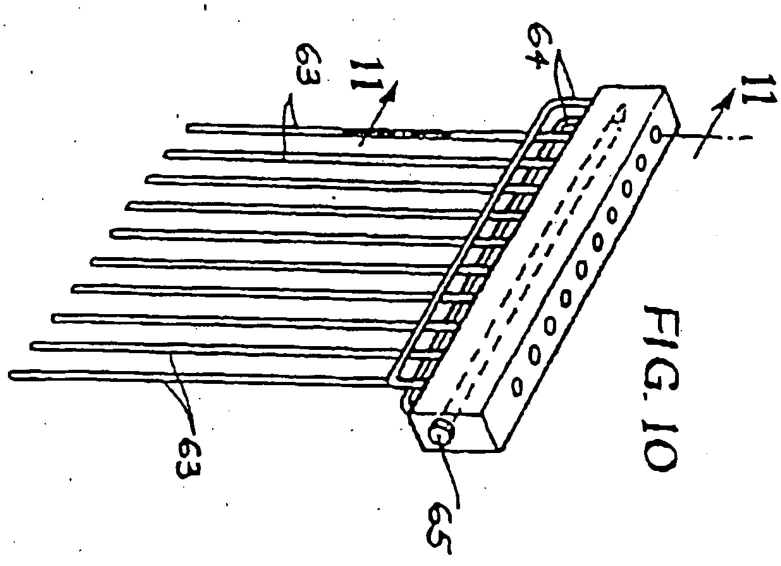


FIG. 10

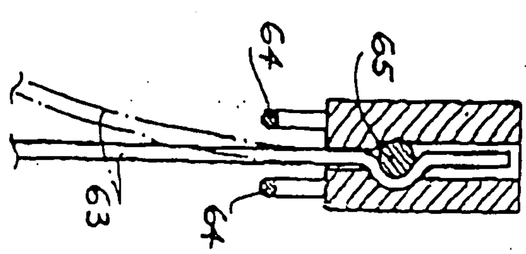


FIG. 11

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